CENTER OF EXCELLENCE IN ENVIRONMENTAL TOXICOLOGY (CEET)

Environmental Health Science Focused Research Pilot Project Grants

Grants up to $50,000 available per project

Supported by the National Institute of Environmental Health Sciences (NIEHS) Grant #2 P30 ES013508

Application Packet

Background

The Center of Excellence in Environmental Toxicology (CEET) announces the following **Focused Research** pilot project opportunity.

Applications are due by **Monday, August 30, 2021**.

Focus Research Awards:

Applications related to the following four (4) thematic areas are currently being accepted:

1. **Air Pollution and Lung Health**
2. **Environmental Exposures and Cancer**
3. **Windows-of-Susceptibility**
4. **Environmental Neuroscience**

Applicants who submitted in a previous funding cycle and were unfunded and encouraged in their decision letter may submit a revised application.

Deadlines and Notifications

All applications will be sent out for peer-review to experts in the field, the CEET Executive Committee will then meet to select the awardees. Each application will be scored using the NIH scoring system (refer to the '**application review criteria**' section). Below are the application deadlines and timeline.

Application Deadline	CEET Executive Committee Meeting	Award Notification	Award Start Date
By Monday August 30, 2021	**By Friday September 17, 2021**	**By Friday September 24, 2021**	**Friday, October 1, 2021**

Center of Excellence in Environmental Toxicology (CEET)
Environmental Health Science Focused Research Pilot Project Grant Application

Eligibility Requirements

1. Any standing or research faculty member from any University of Pennsylvania School may apply
2. Preference will be given to first-time applicants and senior faculty who wish to embrace environmental health or toxicology research as a new direction
3. Preference will be given to applications that are likely to lead to grant funding from the National Institute of Environmental Health Sciences (NIEHS)
4. Preference will be given to research projects that will utilize one or more of the CEET Facility Cores
    - Integrative Health Sciences Facility Core
    - Translational Biomarker Core
    - Exposure Biology Informatics Core
5. The research being proposed cannot be funded by an external funding agency

Funding/Reporting Requirements

The anticipated period of funded project performance will be for 12 months following the project start date.

Funded applications **must** meet the following compliance guidelines.

1. All IRB and IACUC protocols must be in place before the funding can be awarded. A copy of the approved protocols and approval letter should be submitted to the CEET before an award notice can be issued. For more information, see 'IRB and IACUC' in the Full Application Instructions section below.
2. Submit an annual progress report within 3 months of the end of the funding period - The progress report should follow the same format as that required for an NIH R01 RPPR-progress report
3. Present your findings at a CEET Pilot-Project Progress Seminar within 6 months of the end of the funding cycle
4. Acknowledge the parent P30 grant on all publications with the following language: "This publication was made possible by P30 ES013508 from the National Institute of Environmental Health Sciences, NIH. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIEHS, NIH." It is the responsibility of the P.I to ensure that all papers resulting from the pilot project are submitted to PubMed Central and assigned a PMCID number

Full Application Instructions:

Applications must be submitted in **a single PDF** for internal review to paula.williams@pennmedicine.upenn.edu. Applications should include the following, **in this order**:

1. Application Form (**see attached below**)
2. New Format NIH Biosketch for the P.I. and other co-investigators (limit 5 pages)
3. An abstract – a brief summary of the project (no more than 300 words)
4. Introduction-**Revised Applications Only**. These must include a one page response to the previous critique; and then follow the instructions below.
5. Specific Aims (not more than 1 page) – concise goals of the proposed research and a summary of expected outcomes, including specific objectives
6. Research Strategy (not more than 6 pages)

    - Significance – describe the importance of the problem or critical barrier that the project addresses in Environmental Health Sciences, and explain how the project will improve scientific knowledge, technical capability, or clinical practice if the proposed aims are achieved

- Innovation – describe how the proposed research seeks to shift research practice paradigms and how any methodologies or theoretical concepts that are being developed or used in the project may have an advantage over existing practices
- Approach – describe the overall strategy, methodology, and analyses to be used to accomplish specific aims, including how data will be collected. Discuss potential problems, alternative strategies, and benchmarks of success
- Statistical Plan and Plan for Scientific Rigor & Reproducibility

7. Project Timeline (1 page) – a proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the 12-month period of performance
8. A brief outline of how the results from the pilot study will enable the submission of a subsequent NIEHS/NIH grant and a detailed plan for this subsequent grant submission (not more than 1 page)
9. Separate List of Current and Pending Grant Support using NIH formatting guidelines (**NOTE: this should be a separate document in addition to the Biosketch**)
10. References
11. Budget – an NIH-style budget table of personnel, equipment, supplies, and other estimated costs to perform the proposed project. Travel is not allowed.
12. Budget Justification – a detailed explanation and justification of the funding request. *Non-allowable expenses include:*
    - Faculty salaries
    - Tuition for graduate students
    - Travel expenses
13. Facility Core Usage and Correspondence – The CEET Facility Cores offer technical and research support to Center investigators and Pilot Project awardees. A wide range of capabilities, including biostatistical support, analytical sample preparation/processing, and biological sample measurements are available. Early discussion with Core Directors is strongly encouraged. For information on The CEET's cores and their directors, please click here. CEET Facility Core Directors should be contacted to provide a letter of support as a part of this application. **NOTE: If CEET Facility Cores are NOT proposed to support Pilot Project performance, a written justification must be provided as a part of the application**.

IRB and IACUC

Applications using Vertebrate Animals or Human Subjects must also submit the corresponding sections required in an NIH grant (**see below**). Failure to do so will lead to the application being not considered for funding.

Vertebrate Animals:

1. Proposed Use of Animals
2. Justification for the Use of Animals
3. Veterinary Care
4. Procedures
5. Method of Euthanasia

Protection of Human Subjects

Please completed the Human Subjects form below along with all attachments. (**see attached below**)

Center of Excellence in Environmental Toxicology (CEET)
Environmental Health Science Focused Research Pilot Project Grant Application

Application Form (Please Type)

Name		
Position/Title		
Department		
Please select applicable research area	___Air Pollution & Lung Health (AP) ___Environmental Exposures and Cancer (EC) ___Windows-of- Susceptibility (WS) ___Environmental Neuroscience (EN) ___Opportunity Award – Please List Research Area	
Preferred Phone Number		Preferred Email
Preferred Mailing Address		
Application/Research Title		
Total Funding Amount Being Requested		
Name and Contact Information of Business or Grant Administrator		
Questionnaire		
Are you a CEET Member?	___ Yes	___ No
If CEET Member, please list your Thematic Area(s)		
Are you an Early State Investigator?	___ Yes	___ No
Do you plan to use a CEET Facility Core?	___ Yes	___ No
If so, please indicate which Core(s) you plan to use?	_____ Integrative Health Sciences Facility Core (IHSFC) _____ Translational Biomarker Core _____ The Exposure Biology Informatics Core	
Have you met with a Core Director?	___Yes ___No	
If yes, please list of names of the individuals that you have met with?		
Is a letter of support from a Core Director included with this packet?	___Yes ___No	
If you **do not** plan on using a CEET Facility Core, please provide a written justification here.		
Are there animals included in this study?	____ Yes ____ No	
Are humans Subjects included in this study?	____ Yes ____ No	

Application Check List			
Please provide a 'check' or 'x' next to every item that is included in this application packet.			
Application Form___	Biosketch ___	Abstract ___	Specific Aims ___
Preliminary Studies ___	Methods ___	Research Strategy ___ Statistical Plan	Project Timeline ___
Future Funding Statement ___	Grant Support List ___	References ___	Budget/Budget Justification ___
Facility Core Letter of Support ___	Applicable IRB Approval ___	Applicable IACUC Approval ___	

Center of Excellence in Environmental Toxicology (CEET)

Environmental Health Science Focused Research Pilot Project Grant Application

Human Subjects Questionnaire

Please answer all questions below. Note that some questions require attachments. Please use additional paper as needed to answer questions. NOTE: If your study does not include human subjects, please answer 'no' to question number one. There is no need to answer other questions.

Title of Application	
Name	
Position	
Title	
Contact Information	
Study Title	
SECTION 1 - CLINICAL TRIAL QUESTIONNAIRE:	
1. Does this study involve human participants?	**____ Yes ____ No (If no, stop here)**
2. Are the participants prospectively assigned to an intervention?	**____ Yes ____ No**
3. Is the study a Delayed Onset study? Delayed onset means you can't fully define your plans for the human subjects study in your application. Typically, this means you need initial results from the first part of the grant before finalizing plans for the human subjects portion.	**____ Yes ____ No**
4. Is this study exempt from federal regulations?	**____ Yes ____ No**
If "Yes" to question 4 above, Circle the appropriate exemption number:	**1 2 3 4 5 6 7 8**
5. Is the study designed to evaluate the effect of the intervention on the participants?	**____ Yes ____ No**
6. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	**____ Yes ____ No**
SECTION 2 – STUDY POPULATION CHARACTERISTICS	
1. Conditions or Focus of the Study **Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study.** **If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH)**	
2. Eligibility Criteria	
3. Age Limits – if no limit, enter "N/A"	
4. Inclusion of Women, Minorities, and Children	**Attach as additional document**

5. Recruitment and Retention Plan – not required if Exempt #4	**Attach as additional document**
6. Recruitment Status (Please Select One):	**____Not yet recruiting ____Recruiting ____Enrolling by invitation ____Active ____Not Recruiting ____Completed ____Suspended ____Terminated (Halted prematurely) ____Withdrawn (No Participants Enrolled)**
7. Study Timeline	**Attach as additional document**
8. Enrollment of First Subject – Enter the date and if it is Anticipated or Actual	
9. Inclusion Enrollment Report – Use template to provide information for manual entry into Penn eRA	**See attached form**
SECTION 3 – PROTECTION AND MONITORING PLANS (ATTACH AS ONE SINGLE DOCUMENT)	
1. Protection of Human Subjects	**Attach as additional document**
2. Risks to Human Subjects a. Human Subjects Involvement, Characteristics, and Design b. Study Procedures, Materials, and Potential Risks	**Attach as additional document**
3. Adequacy of Protection Against Risks a. Informed Consent and Assent b. Protections Against Risk c. Vulnerable Subjects, if relevant to your study	**Attach as additional document**
4. Potential Benefits of the Proposed Research to Research Participants and Others	**Attach as additional document**
5. Importance of the Knowledge to be Gained	**Attach as additional document**
6. Is this multi-site?	**____ Yes ____ No**
If yes to the question above, describe the single IRB plan	**Attach as additional document**
7. Data and Safety Monitoring Plan – required for Clinical Trial, optional for all other Human Subjects research	**Attach as additional document**
8. Will a Data and Safety Monitoring Board be appointed for this study? – required for Clinical Trial, optional for all other Human Subjects research	**____ Yes ____ No**
9. Overall structure of the study team - required for Clinical Trial, optional for all other Human Subjects research	**Attach as additional document**

APPLICATION REVIEW CRITERIA:

Applications will be sent out for peer-review to experts in the field, the CEET Executive Committee will then meet to select the awardees.

The major review criteria are and will be scored using the NIH system

1. Significance
2. Approach
3. Innovation
4. Investigator
5. Resources & Environment
6. Budget/Budget Justification
7. Likelihood that the project will lead to NIEHS/NIH grant support

Funding will begin **Friday, October 1, 2021** and a Notification of award will be sent to the P.I. and their B.A. **by Friday, September 24, 2021**.

Each application will receive a decision letter and a copy of the critique and scores. If an applicant is encouraged to reapply they must provide a response to the critique (no more than one page).

For questions or more information, contact: Paula Williams
(215) 746-3031
paula.williams@pennmedicine.upenn.edu